

REMARKS/ARGUMENTS

Claims 1, 3-6, 9-15, 17-21, and 24-30 remain in this application.

Rejections Under 35 USC 103

Claims 1, 3-6, 9-15, 17-21, and 24-30 were rejected under 35 USC 103(a) as being unpatentable over Ratnaraj et al. (US 5,658,919) in view of Singh et al. (US 5,759,579) and Robinson et al (US 2003/0049316) and Mukherji et al (US6,565,877). See Pages 2-5 of the Office Action. According to the Office Action:

“Ratnaraj et al. discloses a novel suspension system containing acetaminophenSingh et al. teach a pharmaceutical suspension comprising finely divided pharmaceutically active compounds and liquid excipient suspension system comprising water, and the suspending agents xanthan gum and hydroxypropyl methylcellulose Robinson et al. teach tablets comprising NSAID and/or acetaminophen and wherein the particles are coated with a taste masking composition. The taste masking composition can comprise an insoluble film forming polymer (cellulose acetate or ethyl cellulose) and an enteric polymer (EUDRAGIT E-100). . . . Mukherji et al. teach a taste masked composition comprising an active agent and a coating comprising two enteric polymers . . . It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the combined teachings of Ratnaraj et al (a suspension of acetaminophen) in view of Sing et al. (a suspension of NSAIDs) with Robinson et al. and Mukherji et al. to arrive at the claimed invention. . . . One of ordinary skill would look to the coating compositions of Robinson et al. and Mukherji et al. to coat the drugs of Ratnaraj et al or Singh et al. for the purpose of masking the taste of drugs.”

See Pages 4-5 of the Office Action. Applicants respectfully disagree.

Independent claims 1 and 20 recite dosage forms that comprise particles of an NSAID and/or acetaminophen substantially covered with one layer of a controlled release composition that comprises both an insoluble film forming polymer and an enteric polymer. As noted in the previous amendment dated November 20, 2007, Robinson et al. fails to disclose, or suggest, such particles substantially covered with one layer of a controlled release composition comprising both an insoluble film forming polymer and an enteric polymer. Applicants wish to note that Eudragit E-100 is not an enteric polymer, but rather, as set forth in the attached information on the polymer from its supplier Evonik (Exhibit A), the polymer is soluble in gastric fluid and, accordingly, is not listed by Evonik as an “enteric coating” polymer.

Furthermore, claims 1 and 20 to recite “wherein the weight ratio of the insoluble film forming polymer and the enteric polymer is from about 80:20 to about 99:1.” As discussed above, as Robinson et al fails to disclose, or suggest, particles of an NSAID and/or acetaminophen substantially covered with one layer of a controlled release composition that comprises both an insoluble film forming polymer and an enteric polymer, it certainly also fails to disclose, or suggest, such a particle “wherein the weight ratio of the insoluble film forming polymer and the enteric polymer is from about 80:20 to about 99:1.” As recited in independent claims 1 and 20, from which the remaining claims depend.

With respect to Mukherji et al., it also fails to disclose, or suggest, such particles substantially covered with one layer of a controlled release composition comprising both an insoluble film forming polymer and an enteric polymer. As noted in the Office Action, while it may teach combining two enteric polymers, enteric polymers are not insoluble polymers, as an enteric polymer is soluble at higher pHs.

Furthermore, as discussed above, claims 1 and 20 to recite “wherein the weight ratio of the insoluble film forming polymer and the enteric polymer is from about 80:20 to about 99:1.” As Mukherji et al. fails to disclose, or suggest, particles of an NSAID and/or acetaminophen substantially covered with one layer of a controlled release composition that comprises both an insoluble film forming polymer and an enteric polymer, it certainly also fails to disclose, or suggest, such a particle “wherein the weight ratio of the insoluble film forming polymer and the enteric polymer is from about 80:20 to about 99:1.” As recited in independent claims 1 and 20, from which the remaining claims depend.

Accordingly, Applicants assert that the presently claimed invention would not have been obvious to a person of ordinary skill in the art at the time of the claims invention was made in light of these references. Thus, Applicants respectfully request that this rejection under 35 USC 103(a) be withdrawn.

Conclusion

For the foregoing reasons, the present application is in condition for allowance. Accordingly, favorable reconsideration of the amended claims in light of the above remarks and an early Notice of Allowance are courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned Attorney at the below-listed number.

Serial No. 10/697,840

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750/MCP5021/WEM.

Respectfully submitted,

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